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Shih-Chieh Hung Dept. of Orthop. and Traumetology, Vet. General 201, Sec. 2, Shih-pai Road Hospital-Taipei Taipei, 11217 TAIWAN			DUNSTON, JENNIFER ANN	
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte SHIH-CHIEH HUNG and WAI-HEE LO*

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Appeal 2013-001121  
Application 09/761,893  
Technology Center 1600

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Before DONALD E. ADAMS, MELANIE L. McCOLLUM, and  
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1, 4, 6, 9-11, 34, 35, and 38 (Fin. Rej. 2; *see generally* App. Br. 2).<sup>1</sup> We have jurisdiction under 35 U.S.C. § 6(b).

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<sup>1</sup> Pending claims 12-20 and 43-45 stand withdrawn from consideration (Fin. Rej. 2; *see generally* App. Br. 2).

## STATEMENT OF THE CASE<sup>2</sup>

The claims are directed to a method for isolating mesenchymal stem cells from bone marrow aspirate. Claim 1 is representative and is reproduced in the Claims Appendix of Appellants' Brief.

I. Claims 1, 4, 6, 9, 11, 34, 35, and 38 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Caplan,<sup>3</sup> Prockop,<sup>4</sup> and Matsui.<sup>5</sup>

II. Claims 1, 4, 6, 9, 11, 34, 35, and 38 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Caplan, Burkitt,<sup>6</sup> and Mussi.<sup>7</sup>

III. Claims 1, 4, 6, 9, 11, 34, 35, and 38 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Caplan, Guirguis,<sup>8</sup> and Matsui.

We affirm rejection II. We vacate rejections I and III as cumulative to rejection II.

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<sup>2</sup> We recognize Appellants' "request that the Board ... reverse the withdrawing from consideration of claims 43-45" (App. Br. 3). However, as Examiner explains, this is a petitionable rather than an appealable issue (*see* Ans. 12-13).

<sup>3</sup> Caplan et al., US 5,811,094, issued September 22, 1998.

<sup>4</sup> Prockop et al., US 7,374,937 B1, issued May 20, 2008.

<sup>5</sup> Matsui et al., US 4,871,674, issued October 3, 1989.

<sup>6</sup> H.G. Burkitt et al., Wheater's Functional Histology: A Text and Colour Atlas, 60 (3<sup>rd</sup> ed., Churchill Livingstone, Edinburgh) (1993).

<sup>7</sup> Mussi et al., US 5,409,829, issued April 25, 1995.

<sup>8</sup> Guirguis, US 5,077,012, issued December 31, 1991.

## ISSUE

Does the preponderance of evidence on this record support a conclusion of obviousness?

## FACTUAL FINDINGS (FF)

FF 1. We adopt the Examiner’s findings concerning the scope and content of the prior art (Ans. 7-8).

## ANALYSIS

The claims were not separately argued and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(iv). Claim 1 is representative.

Based on the combination of Caplan, Burkitt, and Mussi, Examiner concludes that, at the time Appellants’ invention was made, it would have been *prima facie* obvious to a person of ordinary skill in this art to modify Caplan’s method of isolating mesenchymal stem cells “to include the introduction of the mixed composition of cells comprising mesenchymal stem cells in medium into the culture insert of” Mussi’s device because Caplan suggests that “it is within the ordinary skill in the art to use a filter to remove red blood cells from cells of bone marrow aspirate”; Mussi suggests “the use of a porous polycarbonate filter membrane” having a pore diameter of “about 0.2 to about 10 microns”; and Burkitt suggests “that red blood cells are the size which would pass through [Mussi’s] filter … while nucleated mesenchymal stem cells … would be retained on top” (Ans. 8-9).

With reference to their arguments addressing the combination of Caplan, *Prockop*, and *Matsui*, Appellants contend that “there was no reason that a person of ordinary skill in the relevant field would combine the prior art elements in the manner claimed and no reasonable expectation of success” (App. Br. 6). Appellants’ contention, however, fails to address the

combination of prior art applied in this rejection, specifically, the combination of Caplan, *Burkitt*, and *Mussi*. Accordingly, we are not persuaded by Appellants' contentions that do not relate to the rejection over the combination of Caplan, Burkitt, and Mussi (*see* FF 1 and Ans. 21-22; *see generally* Ans. 15-16).

Appellants fail to identify the evidence that supports their contention that "a person of ordinary skill in the relevant field would not do the modification," set forth by Examiner over the combination of Caplan, *Burkitt*, and *Mussi* (App. Br. 6). Accordingly, we are not persuaded by Appellants' unsupported contention (*see* FF 1 and Ans. 21-22).

Because the combination of prior art relied upon by Examiner does not include Matsui, we are not persuaded by Appellants' contention relating to Matsui (App. Br. 6; *Cf.* Ans. 22).

We recognize Appellants' contention that "a person of ordinary skill in the relevant field would not modify Caplan's method in view of Burkitt's teaching," because Caplan suggests that bone marrow includes a number of cells, of which red blood cells are only one component, therefore "the removal of red blood cell[s] from aspirated marrow ... [would not result in the isolation of] a pure population of mesenchymal stem cells" (App. Br. 6-7). We are not persuaded for the reasons provided by Examiner (*see* Ans. 23-24).

We recognize, but are not persuaded by, Appellants' contentions regarding an unexpected result (App. Br. 7-8). Specifically Appellants contend that:

1. Prockop suggested that "there is still no generally accepted protocol for isolating and expanding MSC's in culture" (*id.* at 8).

We are not persuaded. As Examiner explains, Appellants contention is based on Prockop’s review of the prior art and discounts Prockop’s disclosure that Prockop’s “invention satisfies this need” (Ans. 14-15 (emphasis removed)). In the context of the rejection over the combination of Caplan, Burkitt, and Mussi, Examiner explains that Caplan, like Prockop, also recognized the need for a “protocol for isolating and expanding MSCs in culture” and disclosed that the Caplan “invention satisfies this need” (Ans. 16 (emphasis removed); *Cf.* App. Br. 8).

2. Appellants “application disclosed that ‘in one preferred embodiment of the present invention, the isolated mesenchymal stem cells proliferate without differentiation and reach confluence even after 12 passages. The cell populations having greater than 98% homogeneous MSCs are obtained in accordance with the method of the present invention’” (App. Br. 8).

We are not persuaded. Appellants’ claim 1 is not limited to this “preferred embodiment” of their invention (*see generally* Ans. 18 and 24; *Cf.* App. Br. 8). In addition, notwithstanding Appellants’ contention to the contrary, Caplan suggests “[c]ompositions having greater than 95%, usually greater than 98% of human mesenchymal stem cells can be achieved using ... [Caplan’s] technique for isolation, purification and culture expansion of MSCs” and Appellants fail to establish that a person of ordinary skill in this art would have reasonably expected that Caplan in combination with Burkitt and Mussi would have produced a different result (Ans. 23-24).

3. Appellants contend that their “unexpected result is supported by post-filing art (Kato et al US Patent Application 20050013804, filing date: 09/12/2001), which mentioned that ‘The conventional

culture methods however cannot produce sufficient amounts of mesenchymal stem cells because the proliferation of said stem cells stops or become extremely slow around the 15<sup>th</sup> generation”” (App. Br. 8).

We are not persuaded. As Examiner explains, “the features upon which applicant relies (i.e., producing a particular amount of stem cells or culture for a particular number of population doublings or generations) are not recited in” claim 1 (Ans. 18).

We recognize, but are not persuaded by, Appellants’ “Remark to the Pre-Appeal Brief Review Summary” (App. Br. 8). As Examiner explains “the features upon which applicant relies (i.e., culture to confluence for 12 passages) are not recited in” claim 1 (Ans. 30).

#### CONCLUSION OF LAW

The preponderance of evidence on this record supports a conclusion of obviousness. The rejection of claim 1 under 35 U.S.C. § 103(a) as unpatentable over the combination of Caplan, Burkitt, and Mussi is affirmed. Claims 4, 6, 9, 11, 34, 35, and 38 are not separately argued and fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

#### TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc